

**13. Diseases of the Musculoskeletal System and Connective Tissue****Reference**

Nishizawa Y, Nishizawa Y, Amenomori Y, et al. A comparison of the analgesic effect of non-steroid anti-inflammatory drugs (NSAIDs alminoprofen) and those of a Chinese traditional herbal medicine, Boi-ogi-to and Shuchi-Bushi-Powder on osteoarthopathy of the knee joint in middle-aged and elderly patients with knee-joint osteoarthopathy. *Itami to Kampo (Pain and Kampo Medicine)* 1998; 8: 17-32 (in Japanese with English abstract). Ichushi Web ID: 1999041737

**1. Objectives**

To compare the efficacy of Kampo medicines (boiogito [防己黄耆湯] and shuchibushimatsu [修治附子末]) with NSAIDs for improving analgesia, quality of life (QOL), and exercise capacity in patients with knee osteoarthritis.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

Three clinics, one hospital, and the Department of Anesthesiology, Shiga University of Medical Science, Japan.

**4. Participants**

One hundred and fifty patients with knee osteoarthritis associated with knee pain and swelling who were candidates for surgery or required steroid treatment were included after 9 detailed exclusion criteria were applied.

**5. Intervention**

Arm 1: Kampo formulations only. Oral administration of Boiogito (防己黄耆湯) (manufacturer, not specified) 0.125 mg/kg/day + shuchibushimatsu (修治附子末) (manufacturer, not specified) 15 mg/kg/day on an empty stomach with 350 mL of water at 6:00, 14:00, and 22:00 for 1 year (2 males and 48 females: n=50; mean age, 65.7±7.3).

Arm 2: NSAIDs and Kampo formulations. Oral administration of NSAIDs (alminoprofen 600 mg/day) + boiogito (防己黄耆湯) (manufacturer, not specified) 0.125 mg/kg/day + shuchibushimatsu (修治附子末) (manufacturer, not specified) 15 mg/kg/day for 1 year (4 males and 46 females: n=50; mean age, 65.3±7.8).

Arm 3: NSAIDs only. Oral administration of alminoprofen 600 mg/day for 1 year (3 males and 47 females: n=50; mean age, 64.5±8.1).

**6. Main outcome measures**

Pain assessment using a visual analog scale for pain (VAS-P) every month and face rating score (FRS) at the start and end of the study. The physical, mental, economic, social, and pharmacological aspects of quality of life (QOL) assessed using VASs at the start and end of the study. Motor function assessed by the Japanese Orthopaedic Association (JOA) score and others.

**7. Main results**

Before the study began, there were no between-group differences in VAS-P and FRS. After 1 year of treatment, both measures improved in arms 1 > 2 > 3 and for each month differed significantly between arms 1 and 3 ( $P<0.01$ ), as well as arms 2 and 3 ( $P<0.05$ ). Total QOL improved in arm 1 ( $202.9\pm28.5\%$ ) > 2 ( $180.6\pm28.3\%$ ) > 3 ( $125.0\pm11.4\%$ ), showing significant differences between arms 1 and 3 ( $P<0.01$ ), as well as arms 1 and 2 ( $P<0.01$ ). Exercise capacity showed similar results. For arm 1, the response was marked in 33 patients (67.3%), moderate in 15 (20.4%), mild in 2 (4.1%), absent in 2 (4.1%), worse in 2 (4.1%) with 1 dropout (due to relocation); for arm 2, the response was marked in 15 patients (31.3%), moderate in 8 (16.7%), mild in 5 (10.4%), absent in 3 (6.3%), worse in 17 (35.4%), with 2 dropouts (due to relocation); for arm 3, the response was marked in 4 patients (8.3%), moderate in 5 (10.4%), mild in 7 (14.6%), absent in 5 (10.4%), worse in 27 (56.8%), with two dropouts (due to relocation). The response rates were higher in arms 1 > 2 > 3, and differed significantly between arms 1 and 3 and between arms 2 and 3 ( $P<0.01$  for both comparisons).

**8. Conclusions**

Kampo medicine is useful for the treatment of elderly patients with knee osteoarthritis.

**9. From Kampo medicine perspective**

The authors stated that arthralgia and neuralgia correspond to “wind-dampness (風湿)” and edema corresponds to “heavy body (身重)”.

**10. Safety assessment in the article**

The proportion of patients with adverse effects or abnormal laboratory test results were greater in arms 3 > 2 > 1; the number of cases were reported without giving details.

**11. Abstractor's comments**

This study was considered an RCT because the allocation was made using a random number table. Unfortunately, it was not conducted in a blind manner, but was well designed as a whole. As knee osteoarthritis is common in the elderly and NSAIDs have adverse effects, there are great expectations for Kampo medicines.

**12. Abstractor and date**

Tsuruoka K, 24 April 2008, 1 June 2010, 31 December 2013.